



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



*[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]*

**Issued:** September 28, 2012

**Posted:** October 5, 2012

[Name and address redacted]

### **Re: OIG Advisory Opinion No. 12-13**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal by a hearing aid supplier to begin billing Medicare for certain audiometric testing, while continuing to offer free hearing tests to prospective hearing aid customers (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the “Act”), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the

Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## **I. FACTUAL BACKGROUND**

[Name redacted] (the “Requestor”) operates a chain of hearing aid supply and service locations in [state name redacted]. The Requestor’s staff, which includes Medicare-qualified audiologists, regularly fit and dispense hearing aids and also administer tests of ear functions such as hearing and balance.

Both hearing aids and examinations for the purpose of prescribing, fitting, or changing hearing aids are excluded from Medicare coverage. See section 1862(a)(7) of the Act; 42 C.F.R. § 411.15(d). However, certain types of air, bone, and speech audiometric tests (the “Audiometric Testing”)<sup>1</sup> may be covered by Medicare Part B, if performed according to applicable coverage rules. One of the coverage rules requires that the Audiometric Testing be performed on the basis of a physician’s or other prescribing provider’s prescription or order.<sup>2</sup> Despite the availability of coverage for properly performed Audiometric Testing, however, the Requestor certified that to date it has never billed Medicare for such testing.

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<sup>1</sup> The Audiometric Testing is comprised of procedures represented by the following short descriptions and codes: “Pure tone audiometry air,” CPT 92552; “Audiometry air & bone,” CPT 92553; “Speech threshold audiometry,” CPT 92555; “Speech audiometry complete,” CPT 92556; and “Comprehensive hearing test,” CPT 92557; and “Tympanometry,” CPT 92567.

<sup>2</sup> Other applicable Medicare Part B coverage rules for the Audiometric Testing include: the testing must be performed by Medicare-qualified and enrolled audiologists and must serve certain purposes, such as, evaluation of suspected change in hearing, tinnitus and balance. See The Centers for Medicare & Medicaid Services, “Medicare Benefit Policy Manual,” Pub. 100-02, Chapter 15, section 80.3.

Under the Proposed Arrangement, the Requestor would begin billing Medicare for the Audiometric Testing when permitted by applicable coverage rules. The Requestor would also continue to offer walk-in customers free hearing tests to promote the sale of hearing aids (the “Free Hearing Exam”). The Free Hearing Exam involves four diagnostic procedures,<sup>3</sup> which partially overlap with the procedures involved in the Audiometric Testing. The Requestor certified that the Free Hearing Exam is offered to customers without regard to their insurance coverage, health status, or whether the customers purchase any goods or services from the Requestor. The Requestor does not bill these tests to Medicare, and obtaining the Free Hearing Exam does not qualify one for Medicare coverage of any items or services. The Requestor stated that the Free Hearing Exam’s retail value is greater than \$10.

The Requestor certified that it does not and would not recommend that a customer receiving the Free Hearing Exam subsequently undergo the Audiometric Testing paid for by the Medicare program. Neither would the Requestor attempt to obtain on behalf of that customer the physician prescription or order that would be required for Medicare coverage of the Audiometric Testing. The Requestor certified that it would only bill Medicare for the Audiometric Testing when that testing was performed on the basis of the prescription or order of the customer’s own physician or other prescribing provider and in accordance with applicable coverage rules. The Requestor’s staff does not recommend to customers the services of any particular physicians or other prescribing providers from whom Federally billable services or prescriptions or orders for Federally billable services can be obtained. The Requestor neither contracts with nor employs physicians or other prescribing providers who prescribe or order Federally billable health care services for customers.

## **II. LEGAL ANALYSIS**

### **A. Law**

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration”

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<sup>3</sup> The Requestor’s staff perform four procedures in the Free Hearing Exam: 1) taking a case history; 2) otoscopic examination; 3) puretone air and bone conduction testing; and 4) speech reception threshold and speech discrimination.

includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (the “CMP”) provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) as including “transfers of items or services for free or for other than fair market value.” The OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the statute,” and has interpreted “nominal in value” to mean “no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24,400, 24,410—11 (Apr. 26, 2000) (preamble to the final rule on Civil Money Penalties).

## **B. Analysis**

The Proposed Arrangement, under which the Requestor would start to bill Medicare for Audiometric Testing while continuing to provide the Free Hearing Exam to walk-in customers (including Medicare beneficiaries), implicates both the civil monetary penalty prohibiting beneficiary inducements and the anti-kickback statute. Arrangements whereby a prospective provider or supplier of Federally payable items and services offers beneficiaries a non-covered item or service free of charge implicate these fraud and abuse laws and must be closely scrutinized.

For the reasons set forth below, we nonetheless conclude that the Proposed Arrangement presents a minimal risk of Federal health care program abuse, and we would not seek to impose administrative sanctions in connection with the statutes discussed above.

We begin with the application of the CMP to the facts presented. The threshold question is whether the offer of the Requestor's Free Hearing Exam would constitute remuneration offered or transferred to Medicare or Medicaid beneficiaries, and, specifically, whether that remuneration would be more than nominal in value. The Requestor stated that the four procedures that comprise the Free Hearing Exam have a combined retail value of greater than \$10. The Free Hearing Exam therefore has economic value, and that value is more than nominal.

The next question that we address under the CMP is whether the continued offer of the Free Hearing Exam would be likely to influence beneficiaries to select the Requestor as their provider of Audiometric Testing services payable by Medicare. Under the circumstances certified to by the Requestor, we believe the answer is no.

The Free Hearing Exam is not used to market Audiometric Testing and does not otherwise lead to Audiometric Testing. The Audiometric Testing is payable by Federal health care programs only on a physician's or other prescribing provider's prescription or order. The Requestor certified that it would not recommend that a customer receiving the Free Hearing Exam also undergo the Audiometric Testing, nor would it attempt to obtain a prescription or order for Audiometric Testing on behalf of the customer. The Requestor does not and would not contract with or employ physicians or other prescribing providers that prescribe or order Federally billable items or services such as the Audiometric Testing for the Requestor's customers.

For these reasons, we believe that the offer of the Free Hearing Exam exercises minimal influence over beneficiaries' selection of the Requestor as their provider of Audiometric Testing. Having made this determination, we do not reach the third issue under the CMP (i.e., whether the Requestor knows or should know that the Free Hearing Exam would be likely to influence beneficiaries' selection of the Requestor for Audiometric Testing). For the reasons noted above, we would not impose sanctions on Requestor under the CMP, in connection with the Proposed Arrangement.

Also for the reasons set forth above, we would not impose administrative sanctions on the Requestor in connection with the anti-kickback statute, as a result of the Requestor's billing Medicare for Audiometric Services.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the

Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

#### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestor with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestor with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske  
Chief Counsel to the Inspector General